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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/824,364 | 04/02/2001 | Ismat Ullah | HX96 (DIV) | 7174 |

7590 03/03/2006

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| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

DATE MAILED: 03/03/2006

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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 09/824,364
Filing Date: April 02, 2001
Appellant(s): ULLAH ET AL.

B. Rodney
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 2/2/06 appealing from the Office action mailed 12/23/06.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The summary of claimed subject matter contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

| | | |
|---|---|---|
| H1286 | EISMAN | 2-1994 |
| 5,238,686 | EICHEL | 8-1993 |
| 5,225,202 | HODGES | 7-1993 |
| 5,972,389 | SHELL | 10-1999 |

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 28, 36-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisman in view of Eichel et al, Hodges et al, and Shell et al.

Eisman et al teach a method of lowering cholesterol by administration of a combination of an HMG CoA reductase inhibitor and a pharmaceutical which reduces cholesterol other than by inhibiting HMG CoA reductase (abstract). Lovastatin (column 8 lines 56-59) and aspirin (column 13 line 42) are disclosed. Tablets and capsules are disclosed (column 15 line 10). Antioxidants such as ascorbic acid are disclosed (column 15 line 14).

Eichel et al teach sustained release preparations of aspirin wherein the aspirin

Is uncoated as well as coated with an enteric coat (abstract). Granular drugs are specified (column 5 line 65).

Hodges et al teach enteric-coated pellets (abstract). Pravastatin is specified (table, column 5).

Shell et al teach a plurality of drugs carried by pârticulates, wherein each particulate carries one drug, to vary the release of each drug according to its half-life by varying the release rate of the particles carrying each drug and/or the number of particles carrying the drug (column 9 line 48 column 10 line 4).

It would have been obvious to one of ordinary skill to deliver the composition of Eisman et al with the vehicle of .Eichel et al., to achieve the beneficial effect of controlled release. As to coating statlns as well, Hodges et al. teach such.

It would have been further obvious to one of ordinary skill to place the two drugs of Eisman et al in separate padiculates to achieve the beneficial effect of varying half-life in view of Shell et al.

**(10) Response to Argument**

Applicants argue that the only difference between the dosage form employed in the instant claimed method and the dosage form claimed in the parent patent is that the parent claims are directed to a bilayered tablet whereas the dosage form of the instant claimed method is a tablet or capsule. However, a more accurate characterization of

the dosage form in the instant claimed method is a tablet or capsule containing granules comprising both aspirin and a statin.

Applicants principally argue that the primary reference, Eisman et al not teach a combination of aspirin and statin. However, Eisman et al specifically discloses a statin in combination with other cholesterol lowering agents, including aspirin, which function differently than statins (column 13 lines 25-49). Further, Eisman et al disclose that this second agent may be employed together with the statin in the same dosage form (column 15 lines 60-63).

Applicants argue that Eisman et al do not recognize the purported incompatibility of a statin with aspirin. However, it is argued that Eisman et al teach binders, disintegrants, and other excipients (column 16 lines 30-35), which, when combined with the two active agents, separate them and thereby preventing one from reacting with the other.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

E. Webman

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